Exploring the perspectives of people with stroke, caregivers and healthcare professionals on the design and delivery of a mHealth adaptive physical activity intervention

STUDY PROTOCOL

Exploring the perspectives of people with stroke, caregivers and healthcare professionals on the design and delivery of a mHealth adaptive physical activity intervention: a qualitative study protocol [version 1; peer review: awaiting peer review]

Andrew Hunter[1], Daniel Carter[2], Mairead O'Donoghue[2], Nathan Cardy[2], Jane Walsh[3], Julie Bernhardt[4], Claire Fitzsimons[5], Ita Richardson[2], Jon Salsberg[2], Liam Glynn[2], Cathal Walsh[2], Edina O'Driscoll[6], Pauline Boland[2], Nora Cunningham[7], John Forbes[2], Rose Galvin[2], Sara Hayes[2]

[1]School of Nursing and Midwifery, National University of Ireland, Galway, Galway, Ireland
[2]Health Research Institute, University of Limerick, Limerick, Ireland
[3]School of Psychology, National University of Ireland Galway, Galway, Ireland
[4]Florey Institute of Neuroscience and Mental Health,, University of Melbourne, Victoria, Australia
[5]Physical Activity for Health Research Centre, Institute Sport, Physical Education and Health Sciences,, University of Edinburgh, Scotland., UK
[6]Health Service Executive, Health Service Executive, Ireland, Ireland
[7]University Hospital Limerick, University Hospital Limerick, Limerick, Ireland

v1 **First published:** 13 Oct 2022, **5**:66
https://doi.org/10.12688/hrbopenres.13506.1
Latest published: 13 Oct 2022, **5**:66
https://doi.org/10.12688/hrbopenres.13506.1

Abstract

Background: Despite recent advances in acute stroke intervention, secondary prevention strategies are lacking. Physical activity (PA) is the second-largest predictor of stroke and a cornerstone of secondary prevention therapies. Interventions to promote PA post-stroke include components aimed at reducing sedentary behaviour and increasing participation in lifestyle PA and structured exercise. Despite guidelines to adapt PA to individuals' needs, there is no evidence on the empirical development of adaptive PA interventions post-stroke. This study will explore patient, caregiver and multidisciplinary healthcare professional perspectives on the design and delivery of adaptive, personalised PA interventions, delivered using a smartphone application, following mild-to-moderate stroke. Findings will directly inform the protocol of an experimental trial, using a novel adaptive trial design.

Methods: A descriptive qualitative study will be undertaken to inform the design, delivery and subsequent acceptability of a smartphone

Open Peer Review

Approval Status *AWAITING PEER REVIEW*

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application to reduce sedentary behaviour and promote PA post-stroke. Data will be collected via one-to-one interviews and focus groups and analysed according to a six-step thematic analysis. Findings will be reported in accordance with the consolidated criteria for reporting qualitative research (COREQ) checklist. One-to-one interviews and focus group interviews will be conducted with three stakeholder groups: 1) People post-stroke, who are independently mobile, without communication and cognitive deficits, living in the community, and without other diagnosed neurological conditions. 2) Caregivers (formal and informal) involved in post-stroke care. 3) Healthcare professionals who are members of multidisciplinary stroke teams.

Ethics and dissemination: Ethical approval has been granted by the Faculty of Education and Health Sciences Research Ethics Committee at the University of Limerick [Ref: 2019_10_03_ EHS]. Findings will be shared locally with all stakeholder groups, submitted for publication, and will inform the protocol and conduct for a novel and flexible experimental trial, examining the effectiveness of an adaptive PA intervention post-stroke.

Keywords

Personalised health, stroke, physical activity, adaptive intervention

Corresponding author: Sara Hayes (sara.hayes@ul.ie)

Author roles: Hunter A: Formal Analysis, Funding Acquisition, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Carter D**: Formal Analysis, Investigation, Writing – Review & Editing; **O'Donoghue M**: Formal Analysis, Investigation, Writing – Review & Editing; **Cardy N**: Formal Analysis, Writing – Review & Editing; **Walsh J**: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; **Bernhardt J**: Funding Acquisition, Writing – Review & Editing; **Fitzsimons C**: Funding Acquisition, Investigation, Methodology, Writing – Review & Editing; **Richardson I**: Funding Acquisition, Investigation, Methodology, Writing – Review & Editing; **Salsberg J**: Methodology, Writing – Review & Editing; **Glynn L**: Funding Acquisition, Methodology, Writing – Review & Editing; **Walsh C**: Funding Acquisition, Writing – Review & Editing; **O'Driscoll E**: Funding Acquisition, Writing – Review & Editing; **Boland P**: Methodology, Writing – Review & Editing; **Cunningham N**: Methodology, Writing – Review & Editing; **Forbes J**: Conceptualization, Funding Acquisition, Methodology, Writing – Original Draft Preparation; **Galvin R**: Methodology, Writing – Review & Editing; **Hayes S**: Conceptualization, Formal Analysis, Funding Acquisition, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This study is funded by a Health Research Board Definitive Intervention Feasibility Award (DIFA-2018-023). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: Hunter A, Carter D, O'Donoghue M *et al.* **Exploring the perspectives of people with stroke, caregivers and healthcare professionals on the design and delivery of a mHealth adaptive physical activity intervention: a qualitative study protocol [version 1; peer review: awaiting peer review]** HRB Open Research 2022, **5**:66 https://doi.org/10.12688/hrbopenres.13506.1

First published: 13 Oct 2022, **5**:66 https://doi.org/10.12688/hrbopenres.13506.1

Introduction

Stroke is the second leading cause of death and disability globally and the absolute number of people who have had a new stroke, died, survived or remained disabled from a stroke has almost doubled between 1990 and 2017 (Krishnamurthi *et al.*, 2020). Despite advances in acute stroke intervention, secondary prevention strategies are lacking and therefore require urgent attention (McElwaine *et al.*, 2016). Physical activity (PA) is the second-largest predictor of stroke (O'Donnell *et al.*, 2016) and meta-analytic evidence demonstrates that the five-year risk of recurrent stroke is 26.4% (Mohan *et al.*, 2011). PA levels of community-dwelling people with stroke remain lower than their age-matched counterparts (English *et al.*, 2016), with many spending the vast majority of their waking time sitting down (English *et al.*, 2014). People with stroke have additional barriers to PA, such as muscle weakness, sensory dysfunction, reduced balance, and fatigue (Billinger *et al.*, 2014).

Cohort studies consistently support the association between PA and primary stroke prevention (Kubota *et al.*, 2017; Sattelmair *et al.*, 2010) and PA interventions present as a cornerstone of secondary stroke prevention (Billinger *et al.*, 2014). Interventions to improve PA levels in people post-stroke are often multiple-component and include treatments to reduce sedentary behaviour (SB) - waking time behaviour characterised by low energy expenditure while in a sitting, reclining or lying posture (Tremblay *et al.*, 2017). PA and SB interventions include; programmes to reduce the amount of daily sitting and lying time; programmes to increase habitual lifestyle PA, e.g. take more steps during daily tasks and; programmes to promote structured exercise, e.g. engage in bouts of moderate-to-vigorous structured exercise.

Given the heterogeneous impact of stroke, adaptive PA interventions, which are personalised to individual preference and performance, are recommended (Billinger *et al.*, 2014). Effective clinical management of stroke often requires a sequence of treatments and patient-health professional interactions/foci, each adapted to individual response, and hence multiple treatment decisions throughout the course of an individual's rehabilitation (Murphy, 2005). Despite recommendations to adapt PA to individuals' needs, enacting person-centred care and increasing uptake of such interventions (Jones *et al.*, 2020), there is a lack of empirical data on adaptive PA interventions post-stroke, or the optimum sequence of these treatments. The findings of a Cochrane Review (Saunders *et al.*, 2020) demonstrate small-to-medium, short-term effects in favour of exercise on function. In the pursuit of more definitive and sustainable effects, adaptive study designs are needed, including trials investigating stroke outcomes using repeated randomisation which is responsive to the flexibility needed to adjust for individual patients' needs and preferences. Studies are underway which utilise adaptive design to investigate early mobility following stroke (ANZCTR, 2019). The Sequential Multiple Assignment Randomised Trial design (SMART) (Murphy, 2005) has been developed for the purpose of designing optimal adaptive interventions. SMARTs are factorial designs in a sequential setting (Almirall *et al.*, 2014; Murphy, 2005) and can be described as multi-stage randomised controlled trial designs. Trials that identify non-responders and allow for the empirical adaptation of subsequent PA treatments will realise larger benefits for some and reduce the use of less-effective therapies for many. Repeated randomisations of participants to treatment options could help to develop an optimal adaptive PA intervention for people post-stroke. The use of SMART design has been used to analyse the optimal type and dosage of treatment in adults with knee osteoarthritis who underwent physical therapy and cognitive behavioural therapy (Karp *et al.*, 2019), and has also been used to assess behaviour change interventions in adolescent obesity populations (Naar *et al.*, 2019). To our knowledge, despite their recent popularity in other fields, SMARTs have not yet been reported, which assess the effect of interventions to increase PA and reduce or break up SB post-stroke.

Mobile health (mHealth) refers to health-related interventions that are delivered using mobile devices, e.g. smartphones (Agarwal *et al.*, 2016). Smartphone technology presents as a suitable method of delivering adaptive interventions. Despite the potential pragmatism and scalability, information is lacking about the how to design and evaluate a smartphone application to promote PA and promote secondary prevention post-stroke. The findings of a recent Cochrane review demonstrate that there is currently not enough evidence (four small RCTs with 274 participants) to support the use of activity monitors to increase PA after stroke, with authors outlining the need for further research (Lynch *et al.*, 2018).

Given the degree of tailoring permitted in an adaptive PA intervention, delivered using mobile technology post-stroke, complexity will be inherent in the intervention, as outlined in the MRC guidelines for developing and evaluating complex interventions (Craig *et al.*, 2008). The optimal design of such a complex intervention needs to be informed by key stakeholders and end-users; including a person-centred approach is crucial to identify which features are likely to be most important and acceptable in this population (Yardley *et al.*, 2015). It is becoming increasingly common to conduct qualitative studies prior to more formal intervention design and testing quantitatively, to ensure prospective acceptability of the complex intervention (Sekhon *et al.*, 2017) and so that feasibility of future studies can be ascertained (O'Cathain *et al.*, 2013; Rousseau *et al.*, 2019). Having a genuine and structured stakeholder consultation about all aspects of an intervention as individualised as PA after stroke is key to successful eventual implementation (Hamilton & Finley, 2019). To this end, the aim of this study is to examine the perspectives of people with stroke, their caregivers and healthcare providers on the design and delivery of an adaptive, personalised mHealth intervention to promote PA after stroke. This qualitative study presents as the initial stages of intervention design, it will inform the development of a personalised mHealth intervention to be investigated using a SMART trial.

Methods

Study design

A qualitative study design using a reflexive thematic analysis guided by Braun and Clarke's framework (Braun & Clarke, 2019; Braun & Clarke, 2021) will be used. Focus groups and

one-to-one interviews will be performed with participants from each stakeholder group. The focus groups will be moderated by multiple researchers (SH, NC, MOD, DC) using a prepared semi-structured interview guide. Data will be used to inform the design and technical specifications of a mHealth intervention, including frequency and modality of exercise, and essential key features of a mHealth application. The COREQ standardised reporting guidelines will be followed to standardise the conduct and reporting of the research (Tong *et al.*, 2007).

Research team roles

All focus groups will be moderated, transcribed and analysed by SH, NC, MOD, and DC. SH is a lecturer in physiotherapy and, as the principal investigator, has led on the conceptualisation of this research and will contribute to the analysis and dissemination stages. NC is a postdoctoral researcher and clinical specialist physiotherapist with experience in multidisciplinary health interventions, developing rehabilitation guidelines and tracking outcome of treatment interventions. NC will play a role in data collection, analysis and dissemination. MOD and DC are postgraduate researchers working in the capacity of research assistants. Both have completed training in qualitative research methods at the postgraduate level and are involved separately in their own original qualitative research as part of their doctoral dissertations. AH is an experienced qualitative researcher and will provide critical feedback and support throughout the design, analysis and dissemination stages. All other team members have contributed to the conceptualisation of this research and will contribute to the analysis and dissemination stages.

Sample size

It is envisaged that approximately ten participants each per stakeholder group (people post stroke, caregivers and multidisciplinary members of stroke teams) will participate in either one-to-one interviews or focus groups, allowing for patient preference. It is anticipated that there will be approximately 30 participants overall.

Recruitment and participants

Participants will be recruited purposively. People with stroke will be recruited through University Hospital Limerick (UHL), University College Hospital Galway (UCHG), the ULEARN-GP network, a nationally representative network of general practices, (O'Regan *et al.*, 2020) and local, community-based stroke support groups. Recruitment letters and the study information sheet with contact details for the study investigators will be sent through a gatekeeper at the support groups. Inclusion criteria for people with stroke will include: a confirmed diagnosis of stroke, aged 18 years or more, independently mobile, community-dwelling, without other diagnosed neurological conditions and with sufficient cognitive and communication ability to take part in the study.

Caregivers will be recruited from local, community-based support groups for caregivers, e.g. Headway, Acquired Brain Injury Ireland, and the Irish Heart Foundation. Invitation letters and participant information leaflets will be sent through a gatekeeper from at each organisation which runs a caregivers' support group. Inclusion criteria for carers will include: caregivers, spouses or family members who provide care (paid or unpaid), support or assistance to people post-stroke and be aged 18 years or more.

Healthcare professionals will be recruited through the email lists of professional bodies, e.g. the Irish Society of Chartered Physiotherapists and the Association of Occupational Therapists of Ireland, and by Twitter. Recruitment emails and the participant information sheet and consent form will be provided to be distributed to their members. Inclusion criteria will include membership with their professional body and employment as a physiotherapist, occupational therapist, speech and language therapist, doctor, nurse, social worker or psychologist.

Data collection

It is envisaged that one-to-one interviews will last between 30 and 40 minutes and that the focus groups will last between 50–60 minutes. To ensure maximising relevance of data across the participant groups and to ensure relevance an interview schedule has been developed in advance (Sandelowski, 2010). The schedule allows for open ended questioning on key topics across all participants. All interviews will be audio recorded, anonymised to ensure confidentiality and transcribed verbatim by professional transcribers and checked by the research team for accuracy.

Patient and public involvement

Patients and caregivers will inform the subsequent design of an adaptive physical activity intervention, through participation in this qualitative study. An additional stage of patient and public involvement will be during the software development stage when key stakeholders will also be invited to review and inform prototypes of the mHealth app, by the app developer.

COVID-19 contingency planning for data collection

Secondary to the ongoing pandemic, changes to the original study design have been made. Where the planned focus groups described above are unable to be held due to pandemic precautions, they will be replaced by one to one interview. To accommodate participants, data will be collected over the phone, Skype or Microsoft Teams.

Interview guides

The Capability, Opportunity and Motivation (COM-B) model was used to inform the development of the interview scripts for all three stakeholder groups. The structure of all three interview guides was informed by the template for intervention description and replication (TIDieR) checklist (Hoffmann *et al.*, 2014).

Analysis

After verbatim transcription of the focus groups, qualitative data analysis will be undertaken by five members of the research team (SH, AH, NC, M'OD, DC). The one-to-one interviews and focus groups will be anonymised and transcribed verbatim, to ensure confidentiality. The digital transcripts will be stored

in a password protected database. Analysis of all data will be undertaken consecutively, according to a six-step procedure (Braun & Clarke, 2021; Braun & Clarke, 2019; Braun & Clarke, 2006): (1) transcription data will be re-read and checked against the audio to ensure accuracy, with researcher notes taken to identify features of interest such as non-verbal sounds, hesitations and humour; (2) pertinent data will be coded; (3) codes will be ordered into provisional themes; (4) the analysis team will compare and discuss themes with a view to consolidating similarities and removing non-applicable data; (5) ongoing focusing and elaboration of the themes will be undertaken to explicate the relationships and differences within and across themes in an effort to best narrate the story present within the data; (6) the final results will be presented, supported with explanatory transcript excerpts to best describe and explain the meaning captured within the themes.

NVivo (version 12.6.1) software will be used to store, code and allow rigorous qualitative analysis. As noted where it is not possible to hold focus groups, particularly in light of the COVID-19 pandemic, one to one interviews will be conducted by phone or virtually. Analysed findings will be used to inform the design and technical specifications of a mHealth intervention, including frequency and modality of exercise, and essential key features of a mHealth application. QualCoder is a free-to-use alternative to Nvivo for data analysis.

Rigour

Rigour will be ensured in a number of ways. Triangulation during analysis will be achieved by utilising five researchers, along with the application of coding stripes within Nvivo to maximise researcher agreement (Bazeley & Jackson, 2013). Similarly, annotation within Nvivo allows for transparent decision making between the five researchers, reducing bias and providing a clear audit trail. Reflexivity is a key component of Braun and Clarke's approach to thematic analysis (Braun & Clarke, 2019) and increasingly is regarded as a marker of quality in qualitative evidence and to that end all analysts will maintain a record their pre-suppositions about this topic in advance of data collection, keep field notes during and after interviews, record memos on development of themes and the influences on same.

Study status

Data analysis is underway.

Ethics and dissemination

Ethical approval has been granted by the Faculty of Education and Health Sciences Research Ethics Committee at the University of Limerick [Ref: 2019_10_03_ EHS]. The findings will be presented locally to attendees of local stroke support groups, in addition to interdisciplinary HCPs and caregivers. The findings will be, submitted for publication and presented at relevant national and international academic conferences.

Conclusion

This study presents the opportunity to gain the perspectives of key stakeholders on the design and delivery of a personalised, adaptive intervention to promote PA post-stroke. By using these key perspectives to enhance the design of a future trial in this area, substantial contributions to stroke recovery research will be made. Pioneering the use of this novel experimental trial design to empirically construct an adaptive PA program will permit the delivery of optimal sequences of treatments to increase PA for individuals. It is envisaged that the current study will lead to advances in secondary prevention practice and policy post-stroke.

Data availability

No data are associated with this article.

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